


**PATENT COOPERATION TREATY**  
**PCT**  
**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**  
(Chapter II of the Patent Cooperation Treaty)  
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 121772	<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416
International application No. PCT/AU2005/000067	International filing date (day/month/year) 21 January 2005	Priority date (day/month/year) 22 January 2004	
International Patent Classification (IPC) or national classification and IPC  Int. Cl.  A61F 2/24 (2006.01)			
Applicant  AUSTRALIAN SURGICAL DESIGN AND MANUFACTURE PTY LIMITED et al			

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p style="margin-left: 20px;">a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of 6 sheets, as follows:</p> <div style="margin-left: 40px;"> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> </div> <p style="margin-left: 20px;">b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>																									
<p>4. This report contains indications relating to the following items:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 5%;"><input checked="" type="checkbox"/></td> <td style="width: 20%;">Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>		<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input checked="" type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
<input checked="" type="checkbox"/>	Box No. I	Basis of the report																							
<input type="checkbox"/>	Box No. II	Priority																							
<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability																							
<input checked="" type="checkbox"/>	Box No. IV	Lack of unity of invention																							
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement																							
<input type="checkbox"/>	Box No. VI	Certain documents cited																							
<input type="checkbox"/>	Box No. VII	Certain defects in the international application																							
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application																							

Date of submission of the demand 31 October 2005	Date of completion of this report 15 February 2006
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer <div style="text-align: center;">   <b>DAVID MELHUIH</b> </div> Telephone No. (02) 6283 2426

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/AU2005/000067

**Box No. I**      **Basis of the report****1. With regard to the language, this report is based on:**

- ☒ The international application in the language in which it was filed
- ☐ A translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3(a) and 23.1 (b))
  - ☐ publication of the international application (under Rule 12.4(a))
  - ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

**2. With regard to the elements of the international application, this report is based on** (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1 – 9, 11 – 13 as originally filed/furnished
- pages\* received by this Authority on \_\_\_\_\_ with the letter of \_\_\_\_\_
- pages\* 10 received by this Authority on 31 October 2005 with the letter of 31 October 2005
- ☒ the claims:
- pages as originally filed/furnished
- pages\* as amended (together with any statement) under Article 19
- pages\* received by this Authority on \_\_\_\_\_ with the letter of \_\_\_\_\_
- pages\* 14 – 18 received by this Authority on 9 February 2006 with the letter of 9 February 2006
- ☒ the drawings:
- pages 1/5 – 5/5 as originally filed/furnished
- pages\* received by this Authority on \_\_\_\_\_ with the letter of \_\_\_\_\_
- pages\* received by this Authority on \_\_\_\_\_ with the letter of \_\_\_\_\_

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

**3. ☐ The amendments have resulted in the cancellation of:**

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to the sequence listing (*specify*):

**4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to the sequence listing (*specify*):

\* If item 4 applies, some or all of those sheets may be marked "superseded."

**Box No. III**      **Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos: 23, 24, 25 (in part), 26 (in part)

because:

☐ the said international application, or the said claims Nos.

relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos.  
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos.  
are so inadequately supported by the description that no meaningful opinion could be formed (*specify*)

☒ no international search report has been established for said claim Nos. 23, 24, 25 (in part), 26 (in part)

☐ A meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ Furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ Furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ Pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b) and 13ter.2.

☐ A meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

**Box No. IV Lack of unity of invention**

1. ☐ In response to the invitation to restrict or pay additional fees the applicant has, within the applicable time limit:
- ☐ restricted the claims
  - ☐ paid additional fees
  - ☐ paid additional fees under protest and, where applicable, the protest fee
  - ☐ paid additional fees under protest but the applicable protest fee was not paid
  - ☐ neither restricted the claims nor paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:
- ☐ complied with.
  - ☒ not complied with for the following reasons:

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1 to 22, 25 (in part), 26 (in part) directed to a heart valve comprising an annular body portion and a support ring, wherein the annular body portion is rotatable relative to the support ring. It is considered that the relative rotation between the body portion and the support ring comprises a first "special technical feature".
2. Claims 23, 24, 25 (in part), 26 (in part) directed to a heart valve comprising an annular body portion and a support ring, wherein the body portion is mounted to the support ring so as to be moveable from a sealed position to a position defining a second fluid pathway between the body portion and the support ring. It is considered that the second fluid pathway comprises a second special technical feature.

Since the abovementioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept, a priori.

4. Consequently, this report has been established in respect of the following parts of the international application:

- ☐ all parts.
- ☒ the parts relating to claims Nos. 1 – 22, 25 (in part), 26 (in part)

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/AU2005/000067

**Box No. V** Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims 1 – 22, 25, 26	YES
	Claims	NO
Inventive step (IS)	Claims 1 – 22, 25, 26	YES
	Claims	NO
Industrial applicability (IA)	Claims 1 – 22, 25, 26	YES
	Claims	NO

## 2. Citations and explanations (Rule 70.7)

### Claims 1 – 22, 25, 26:

Claims 1 to 22, 25 and 26 meet the requirements of PCT Articles 33(2) – (4). None of the prior art documents, or obvious combination thereof, disclose a valve assembly comprising an annular body and a support ring, wherein the annular body and the support ring are moveable relative to each other to open up a second fluid pathway through the valve assembly. The claims are therefore novel and inventive. The claims also have industrial applicability.